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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2021-P-1097 and FDA-2021-P-1111]

Determination That PEPCID (Famotidine) for Oral Suspension, 40 Milligrams/5 Milliliters, Was Not Withdrawn from Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that PEPCID (famotidine) for oral suspension, 40 milligrams (mg)/5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for PEPCID (famotidine) for oral suspension, 40 mg/5 mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence

Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PEPCID (famotidine) for oral suspension, 40 mg/5 mL, is the subject of NDA 019527, held by Bausch Health US, LLC, and initially approved on February 2, 1987. PEPCID is indicated in adults for the treatment of active duodenal ulcer (DU); active gastric ulcer; symptomatic nonerosive gastroesophageal reflux disease (GERD); erosive esophagitis due to GERD, diagnosed by biopsy; treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple endocrine neoplasias); and reduction of the risk of DU recurrence. PEPCID is indicated in pediatric patients 1 year of age and older for the treatment of peptic ulcer, and GERD with or without esophagitis and ulcerations. PEPCID is indicated in pediatric patients from birth to less than 1 year of age for the treatment of GERD.

In a letter received on January 11, 2019, the applicant notified FDA that PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Ajanta Pharma USA Inc., submitted a citizen petition dated October 11, 2021 (Docket No. FDA-2021-P-1097), and Lachman Consultant Services, Inc., submitted a citizen petition dated October 13, 2021 (Docket No. FDA-2021-P-1111), both under 21 CFR 10.30, requesting that the Agency determine whether PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that PEPCID (famotidine) for oral suspension, 40 mg/5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PEPCID (famotidine) for oral suspension, 40 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PEPCID (famotidine) for oral suspension, 40 mg/5 mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PEPCID (famotidine) for oral suspension, 40 mg/5 mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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